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			ART UNIT	PAPER NUMBER
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			06/10/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/570,734	<b>Applicant(s)</b> PALOMERA ET AL.	
	<b>Examiner</b> RONALD T. NIEBAUER	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,9,10,12,13 and 15-25 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,9,10,12,13 and 15-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/31/10</u> .   | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1654

### **DETAILED ACTION**

Applicants amendments and arguments filed 3/31/10 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Previously, Applicant's elected with traverse Group 1 (claims 1,9-10,12-13,15-23) and the following species: [Nε(Me)3-Lys8,(4S)-MeHex14]-KF (compound 93 disclosed in example 10) in the reply filed on 6/19/09. The elected species was found to be free of the prior art. However, since no claim reads solely on the elected species no claim is indicated as allowable. In accord with section 803.02 of the MPEP, the search was extended to other species. As discussed below art was found on other species that read on the instant claims.

Claims 24-25 are to a non-elected group.

Claims 24-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/19/09.

Claims 2-8,11,14 have been cancelled.

Claims 1,9-10,12-13,15-23 are under consideration.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 3/31/10 has been considered by the examiner.

### ***Specification***

As set forth previously, the disclosure is objected to because of the following informalities:

37 CFR 1.52(b)(5) states: "Other than in a reissue application or reexamination proceeding, the pages of the specification including claims and abstract must be numbered consecutively, starting with 1, the numbers being centrally located above or preferably below, the text." In the instant case, the pages of the specification have not been numbered.

The tables on pages 62-80 appear to use commas in numerous locations where it seems that periods would be appropriate. For example, the first entry on page 62 is 3,27E-07. It would seem that 3.27E07 is the appropriate entry.

Appropriate correction is required.

### ***Response to Arguments - Specification***

Applicants argue (pages 8-9) that the use of commas is conventional according to British/European usage and the MPEP refers to using British English spellings.

Applicants argue that the application has been published and thus page numbers are not required.

Applicant's arguments filed 3/31/09 have been fully considered but they are not persuasive.

Although Applicants argue (pages 8-9) that the use of commas is conventional according to British/European usage and the MPEP refers to using British English spellings, it is first noted that a British English spelling is separate and distinct from a comma. A comma is not a spelled

Art Unit: 1654

out word. Further, that statement that the use of commas is conventional is an assertion and a general statement. The fact remains that pages 62-80 appear to use commas in numerous locations where it seems that periods would be appropriate. For example, the first entry on page 62 is 3,27E-07. It would seem that 3.27E07 is the appropriate entry.

Although Applicants argue that the application has been published and thus page numbers are not required, such an assertion is inconsistent with 37 CFR 1.52(b)(5) which states: “Other than in a reissue application or reexamination proceeding, the pages of the specification including claims and abstract must be numbered consecutively, starting with 1, the numbers being centrally located above or preferably below, the text.” The fact remains that the pages of the specification have not been numbered.

### ***Claim Rejections - 35 USC § 112***

The 112 2<sup>nd</sup> and 112 1<sup>st</sup> rejections set forth below appeared in the previous office action. The rejections are maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 21** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1654

Claim 21 is drawn to a compound. Claim 21 refers to '(4RS)-MeHex. With respect to '(4RS)-MeHex', the specification sets forth the meaning of the abbreviation MeHex (page 15). Although the art recognizes 'R' and 'S' stereochemistry notations, for example (4R)-MeHex and (4S)-MeHex, the notation (4RS) is unclear. It is unclear if the stereochemistry is classified as R or S. It is unclear if 'RS' indicates that there can be either R or S or if the intent is that there is a combination of R and S. A single compound is not necessarily the equivalent of two compounds. As such, there is more than one reasonable interpretation of the claims.

***Response to Arguments – 112 2nd***

Applicants argue (page 9) that a racemate is defined as an equimolar mixture of a pair of enantiomers.

Applicant's arguments filed 3/31/09 have been fully considered but they are not persuasive.

Although Applicants argue (page 9) that a racemate is defined as an equimolar mixture of a pair of enantiomers such argument supports the lack of clarity of the instant claim. First, it is noted that claim 21 is drawn to a compound. It is unclear how a compound can be represented by multiple, different structures. A single compound is not necessarily the equivalent of two compounds. As such, it is unclear which structure or structures are required to meet the claim limitations.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1654

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1,9-10,12-13,15-23** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that ‘the inventor invented the claimed invention.’ Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”). Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.” *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

“A written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula, [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) (“In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other

Art Unit: 1654

than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...”) *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is “not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include “level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the



Art Unit: 1654

claimed species is sufficient.” MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

Further, to provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include: a) the scope of the invention; b) actual reduction to practice; c) disclosure of drawings or structural chemical formulas; d) relevant identifying characteristics including complete structure, partial structure, physical and/or chemical properties, and structure/function correlation; e) method of making the claimed compounds; f) level of skill and knowledge in the art; and g) predictability in the art.

In the instant case, the claims are drawn to compounds.

Although unclear (see 112 2<sup>nd</sup>) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined on page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims.

*(1) Level of skill and knowledge in the art/predictability in the art:*

The level of skill in the art is high. There is unpredictability in predicting functional effects of replacements. It is not within the skill of the art to predict any and all derivatives, prodrugs, and residues that would result in compounds in which the resulting compound is an antitumor compound.

Art Unit: 1654

*(2) Scope of the invention/Partial structure/disclosure of drawings:*

In the instant case, the claims are drawn to compounds. Although unclear (see 112 2<sup>nd</sup>) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined on page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims.

In considering the size of the genus, if any 10 of the 14 positions of the compound shown in claim 1 were replaced with any of the 20 naturally occurring amino acids (i.e. derivatives) there are at least  $20^{10}$  (i.e. 10240000000000) different compounds. Further, there are many other compounds possible with non-natural amino acids or compounds that are fragments that are within the scope of the claims.

Although claim 1 recites a compound, the claims are not limited to that compound since the compounds are defined to include derivatives. The claims do not require a significant structural core. A single residue of the compound is not a significant structural core.

The specification, for example, Table VI and claim 15 recites numerous specific compounds, however the compounds represent a small fraction of the possible variety of compounds in the genus. The compounds shown in the examples appear to be limited to modifications at position 8 and 14. However, the specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are

Art Unit: 1654

described as capable of providing a residue of the compound. One of skill in the art would not recognize that applicant was in possession of the claimed genus.

There is substantial variability in the genus. Since there are a substantial variety of compounds possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

*(3) Physical and/or chemical properties and (4) Functional characteristics:*

The title of the application states that the compounds are antitumor compounds. However, there is no specific disclosed correlation between structure and function. It is unclear what structural elements are required for the recited function. The specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. It is unclear which residue, if any, is adequate and sufficient to render the compound antitumor. There are no common attributes or characteristics that identify the compounds. As such, one of skill in the art would not recognize a core structure, common attributes, or features of the compounds. One of skill in the art would not recognize compounds outside of those specifically identified. The teaching in the specification appears to be limited to modifications at positions 8 and 14. It is unclear how to extrapolate possible modifications at positions 8 and 14 to the other positions of the compound.

In particular, no common core sequence is taught. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus and that there is a lack of the knowledge in the art regarding which amino

Art Unit: 1654

acids can vary to maintain the function and thus that the applicant was not in possession of the claimed genus.

*(5) Method of making the claimed invention/actual reduction to practice:*

The specification (see the examples) describes the making of compounds. However, such compounds are not representative of the instant genus which includes derivatives, nor do the compounds provide a specific correlation between structure and function such that one could identify any and all antitumor compounds.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 1,9-10,12-13,15-23 is/are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are many. Although the claims may recite some functional characteristics, the claims lack written description because there is no specific disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outlin[e] goals appellants hope the claimed invention

Art Unit: 1654

achieves and the problems the invention will hopefully ameliorate.”) Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

***Response to Arguments – 112 1<sup>st</sup> written description***

Applicants argue (pages 10-11) that the interpretation of the claims is unreasonable.

Applicants argue that the term derivative does not appear in the claims.

Applicant's arguments filed 3/31/09 have been fully considered but they are not persuasive.

Although Applicants argue (pages 10-11) that the interpretation of the claims is unreasonable, section 2111.01 IV of the MPEP states: “Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim.” Thus, the definition of compound controls the interpretation as used in the claim. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined on page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims.

Although Applicants argue that the term derivative does not appear in the claims, section 2111.01 IV of the MPEP states: “Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim.” Thus, the

Art Unit: 1654

definition of compound controls the interpretation as used in the claim. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined on page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims.

### ***Claim Rejections - 35 USC § 101***

The 101 rejection set forth below appeared in the previous office action. The rejection is maintained.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claims 1,9-10,12-13,15-23** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Albericio teach that kahalalide F is a cyclic depsipeptide isolated from *Elysia rufescens*. On page 2, Albericio show the structure of kahalalide F. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined on page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims. Kahalalide F as shown on page 2 of Albericio also meet the claim limitation of compound since the compound includes a residue, for example Phe (see position 3) of the compounds as claimed.

Art Unit: 1654

Since the compound is present in *Elysia rufescens* it is present in a composition as recited in claim 23.

Although unclear (see 112 2<sup>nd</sup>) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S.

There is no indication that the compounds of the current invention have been isolated or removed from a naturally occurring environment. The claimed subject matter therefore reads on a product of nature.

### ***Response to Arguments – 101***

Applicants argue (page 11) that the language of the claims is ignored.

Applicant's arguments filed 3/31/09 have been fully considered but they are not persuasive.

Although Applicants argue (page 11) that the language of the claims is ignored, section 2111.01 IV of the MPEP states: "Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim." Thus, the definition of compound controls the interpretation as used in the claim. Thus the language of the claim is not ignored since the language of the claim leads on to the definition which controls the meaning. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined on page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims.

***Claim Rejections - 35 USC § 102***

The 102 rejections set forth below appeared in the previous office action. The rejections are maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1,9-10,12-13,15-23** are rejected under 35 U.S.C. 102(b) as being anticipated by Albericio et al (WO 01/58934, cite 1 of IDS 3/6/06).

Albericio teach kahalalide F compounds and mimics thereof (abstract, claims). On page 2, Albericio show the structure of kahalalide F. In example 6 (page 31) Albericio teach the compound 5-MeHex-D-Val-Thr(tBu)-Val-D-Val-D-Pro-Orn(Boc)-D-allo-Ile-D-allo-Thr(Val-Z-Dhb-Phe-H)-D-allo-Ile-D-Val-OH. In the Table on pages 60-63 Albericio teach a variety of other compounds. Albericio teach pharmaceutical compositions of the compounds (page 16 last 2 paragraphs; claim 9). It is noted that claims 1,9-10,12-13,15-22 all refer to a compound. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined in



Art Unit: 1654

page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims. As such, compounds taught by Albericio such as 5-MeHex-D-Val-Thr(tBu)-Val-D-Val-D-Pro-Orn(Boc)-D-allo-Ile-D-allo-Thr(Val-Z-Dhb-Phe-H)-D-allo-Ile-D-Val-OH (example 6 page 31) meet the claim limitation of being a compound since the compound includes a residue, for example Phe (see position 3), of the compounds as claimed. Thus the limitations of claims 1,9-10,12-13,15-23 are met. Further, Albericio teach pharmaceutical compositions of the compounds (page 16 last 2 paragraphs; claim 9) as recited in claim 23. Further, kahalalide F as shown on page 2 of Albericio also meet the claim limitation of compound since the compound includes a residue, for example Phe (see position 3) of the compounds as claimed. It is noted that Albericio teach that alternatives to ornithine include lysine (page 15 2<sup>nd</sup> complete paragraph).

Although unclear (see 112 2<sup>nd</sup>) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S.

**Claims 1,9-10,12-13,15-23** are rejected under 35 U.S.C. 102(b) as being anticipated by Angel Lopez Macia PhD thesis (Jan 18 2001, see the 2nd npl citation of IDS dated 3/11/09).

Macia teach methods of synthesizing kahalalide F (page 4). In section 3.2.2.2 (page 7) Macia teach the compound 5-MeHex-Val-Thr(tBu)-Val-Val-Pro-Orn(Boc)-Ile-Thr(Val-Fmoc)-Ile-Val-ClTrt-PS. It is noted that claims 1,9-10,12-13,15-22 all refer to a compound. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined in page 19. Thus,

Art Unit: 1654

compounds which include a residue of the compounds of the claims are also within the scope of the claims. As such, compounds taught by Macia such as 5-MeHex-Val-Thr(tBu)-Val-Val-Pro-Orn(Boc)-Ile-Thr(Val-Fmoc)-Ile-Val-ClTrt-PS (section 3.2.2.2 page 7) meet the claim limitation of being a compound since the compound includes a residue, for example Val (see position 11), of the compounds as claimed. Further, Macia teach the synthesis (page 28 section 3.2.3.5.2) and purification (Figure 3.29) of KF-1 and KF-2. Since the compounds were purified they were necessarily in a composition as recited in claim 23. Since the compound includes a residue, for example D-Val (see position 13) as the compounds of the instant invention the limitations of claims 1,9-10,12-13,15-23 are met.

Although unclear (see 112 2<sup>nd</sup>) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S.

### ***Response to Arguments – 102***

Applicants argue (pages 11-13) that the language of the claims is ignored.

Applicant's arguments filed 3/31/09 have been fully considered but they are not persuasive.

Although Applicants argue (page 11) that the language of the claims is ignored, section 2111.01 IV of the MPEP states: "Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim." Thus, the definition of compound controls the interpretation as used in the claim. Thus the language of the claim is not ignored since the language of the claim leads on to the definition which controls the meaning. The instant specification (page 19 first complete paragraph) defines compound to

Art Unit: 1654

include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined on page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims. It is noted that the specification expressly states that the compound are defined to include derivatives (page 19). Thus it is reasonable to interpret the compounds to include derivatives (see also MPEP section 2111.01 IV).

### ***Double Patenting***

The double patenting rejections set forth below appeared in the previous office action.

The rejections are maintained.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1654

**Claims 1,9-10,12-13,15-23** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-49 of U.S. Patent No. 7,482,429 ('429). Although the conflicting claims are not identical, they are not patentably distinct from each other.

'429 teach compounds including (claim 1) 5-MeHex-D-Val-Thr-Val-D-Val-D-Pro-Orn-D-allo-Ile-cyclo(D-allo-Thr-D-allo-Ile-Val-Phe-Z-Dhb-Val). The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined in page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims. As such, compounds taught by '429 such as 5-MeHex-D-Val-Thr-Val-D-Val-D-Pro-Orn-D-allo-Ile-cyclo(D-allo-Thr-D-allo-Ile-Val-Phe-Z-Dhb-Val) (claim 1) meet the claim limitation of being a compound since the compound includes a residue, for example D-Val (see position 13), of the compounds as claimed. Further, '429 teach a composition as recited in claim 23. Thus, the limitations of claims 1,9-10,12-13,15-23 are met.

Although unclear (see 112 2<sup>nd</sup>) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S.

**Claims 1,9-10,12-13,15-23** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3,5-13 of copending Application No. 11/587,177 ('177). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Art Unit: 1654

‘177 teach compounds including the compound depicted in claim 3. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined in page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims. As such, compounds taught by ‘177 such as the compound depicted in claim 3 meet the claim limitation of being a compound since the compound includes a residue, for example D-Val (see position 13), of the compounds as claimed. Further, since ‘177 teach the synthesis of the compounds the compounds would be in a composition as recited in claim 23. Thus, the limitations of claims 1,9-10,12-13,15-23 are met.

Although unclear (see 112 2<sup>nd</sup>) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims are directed to an invention not patentably distinct from claims of commonly assigned U.S. Patent No. 7,482,429 and Application No. 11/587,177 as discussed above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 7,482,429 and Application No. 11/587,177, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the

Art Unit: 1654

conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

### ***Response to Arguments – Double Patenting***

Applicants argue (pages 13-14) that the language of the claims is ignored.

Applicant's arguments filed 3/31/09 have been fully considered but they are not persuasive.

Although Applicants argue (page 11) that the language of the claims is ignored, section 2111.01 IV of the MPEP states: "Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim." Thus, the definition of compound controls the interpretation as used in the claim. Thus the language of the claim is not ignored since the language of the claim leads on to the definition which controls the meaning. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as

Art Unit: 1654

defined on page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims. It is noted that the specification expressly states that the compounds are defined to include derivatives (page 19). Thus it is reasonable to interpret the compounds to include derivatives (see also MPEP section 2111.01 IV).

### ***Conclusion***

In the instant case, claims were previously rejected under 112 2<sup>nd</sup>, 112 1<sup>st</sup>, 101, 102, double patenting. The rejections are maintained as discussed above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/  
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/  
Examiner, Art Unit 1654